DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Our Reference Number: 97-1160

May 20, 1999

Ms. Carol Moore
Bayer Corporation
800 Dwight Way
P.O. Box 1986
Berkeley, CA 94701-1986

Dear Ms. Moore:

Your request to supplement your product license application for Antihemophilic Factor (Human) to include a second viral inactivation step in the manufacturing process, has been approved.

We acknowledge receipt of your March 3, 1999 and April 9, 1999 submissions stating that [redacted] will not be used as the primary release test for moisture. The primary method for release will remain the [redacted]

The exemption from lot release under reference number 96-1041 is continued under this supplement. However, you are requested to submit a copy of the release protocol and one sample of a final container from each lot of Antihemophilic Factor (Human) placed into foreign and/or domestic distribution. Please submit the samples and protocols to:

Sample Custodian
HFM-672
5516 Nicholson Lane
Building B, Room 113
Kensington, MD 20895

This information has been placed in your product license file. Please keep a copy of this letter available for review at the time of FDA inspections.

Sincerely yours,

for Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research